

January 23, 2002

To Whom It May Concern:

<u>Pueraria mirifica</u> root has been a traditional medicine widely consumed by Thai people for at least 900 years. It is an indigenous botanical found throughout Thailand that has been recommended by traditional health practitioners for its weak estrogenic properties, similar to recommendations made by traditional practitioners in other parts of Asia who consume soybeans and their by-products. One of the principle reasons for Thai people consuming this root in crude or semi-crude form, or as an extract, is to relieve symptoms associated with the end of menopause in women, which is often referred to as "post-menopausal symptoms", and age-related symptoms in males. Thai people living outside of Thailand, possibly even among Thai communities living in the United States, often return home with <u>P. mirifica</u> root powder for their aging parents or relatives, to continue their family's traditional use of this botanical.

P. mirifica has been available as a traditional medicine in Thailand for over fifty years, and a regulated herbal medicine for the last 10 years. It is a popular herbal medicine today throughout Thailand and even neighboring countries such as Myanmar. Although health claims are not permitted for this botanical, it is offered by more than 25 different Thai manufacturers and can be found readily available in public markets, pharmacies, and health clinics. No prescription is required and it is not registered as a drug but as a food supplement. Toxicology studies in various animals have been conducted at Thai universities on several animal species and been found to be non-toxic at levels of intake well above those recommended for use by Thai manufacturers. Considerable work has been done by Thai university chemists and foreign chemists characterizing the principle compounds found in P. mirifica, with particular interest shown in the isoflavones, many of which are found in soybeans, which is not surprising as P. mirifica is a member of the same botanical family. Since the contents of P. mirifica's isoflavones varies depending on the time of harvest and location, there is increasing demand among health practitioners for the extract of the product to insure consistent levels of the major isoflavones found in the finished product.

Manufacturers generally recommend a daily intake of between 50 to 100 milligrams of the extract or crude powder. No contraindications are known. No significant non-transient adverse events have been reported to date.

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